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EXAMINER
KUBELIK, ANNE R

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1638	16

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/762,105	MALIGA ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *3,6,7 and 18-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-5 and 8-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *with the application* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's election with traverse of group I (claims 1-14) and SEQ ID NO:14 in Paper No. 13, filed 24 February 2003, is acknowledged. The traversal is on the ground(s) that the restriction is improper because it does not follow unity of invention practice for 371 applications. Applicant urges that in the international stage the claims were determined to be drawn to two inventions.

This is not found persuasive. Unity of invention practice requires that inventions that share a single general inventive concept wherein the inventions share a technical relationship among the inventions that involves at least one special technical feature. As stated in the restriction requirement mailed 17 December 2002, Groups I-V do not share a technical feature; Groups I-IV are drawn to plastid transformation and Group V is drawn to mutation of a transgene. The technical feature shared by Groups I-IV is simply a plastid transformation construct. Not all the independent claims recite any other features of the construct (see, for example, claim 18). That technical feature is taught by the prior art, as cited in the restriction. Thus, the technical feature shared by the groups is not special. Furthermore, an examiner is not held to the lack of unity presented in the international stage.

Applicant also urges that the requirement to elect a single sequence is inappropriate and that several pairs of sequences comprise a sequence and a truncated version of that sequence. Applicant thus argues that SEQ ID NOs:14 and 16 should be examined and provides an alignment on pg 4 of the response.

This is not found persuasive because, as can be seen the alignment, SEQ ID NO:16 is not a truncated version of SEQ ID NO:16, wherein the truncation is at one end or the other. SEQ ID NO:16 has an internal deletion relative to SEQ ID NO:14. A search on SEQ ID NO:14 will not

find sequences comprising SEQ ID NO:16; examination of SEQ ID NO:16 would require a separate sequence search. Therefore, SEQ ID NO:16 will not be examined.

Applicant also argues that it is clear from the specification that the plasmids of Groups II and II contain the 5' regulatory regions of Group I and points to the portions of the specification that describe the plasmids. This is found persuasive for plasmids pHK38, and PMSK35, pMSK45, pMSK48 and pMSK49; plasmid pHK40 has the 5' regulatory region of SEQ ID NO:16 and will not be examined for the reasons stated above.

Applicant urges that claims 1-17 and 24-26 should be examined to the extent they read on SEQ ID NOs:14 and 16 and plasmids containing those sequences. Claims 1-17 will be examined to the extent they read on SEQ ID NO:14 and plasmids containing it. Claims 24-26 are drawn to groups of plasmid DNA; as none of these groups comprise only plasmids comprising the elected sequence (see claim 25), claims 24-26 remain restricted.

The requirement is still deemed proper and is therefore made FINAL.

Claim 3 is not drawn to SEQ ID NO:14. Neither of the downstream boxes of claim 6 appear in the elected sequence, SEQ ID NO:14. Neither of the plasmids of claim 7 appear to comprise SEQ ID NO:14. Thus, claims 3 and 6-7, along with claims 18-28 are withdrawn from consideration as being drawn to non-elected inventions. Claims 1-2, 4-5 and 8-17 are examined to the extent they read on plasmids comprising SEQ ID NO:14.

2. The drawings are objected to because Figures 24 and 26 are black boxes. Corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. See 37 CFR 1.85(a) and MPEP 608.02(b).

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

Sequence identifiers are missing from pg 63, lines 3-4, of the specification.

Full compliance with the sequence rules is required in response to this Office action. A complete response to this Office action must include both compliance with the sequence rules and a response to the issues set forth below. Failure to fully comply with both of these requirements in the time period set forth in this Office action will be held to be non-responsive.

Claim Objections

4. Claims 4-5, 8-10, 12-14 and 16-17 are objected to because of the following informalities:

Claims 4, 8-10, 12-14 and 17 start with an improper article.

Claim 5 has an improper article before "DNA" in line 1.

Claim 16 has an improper article before "plasmid" in line 1.

5. Applicant is advised that should claim 2 be found allowable, claim 5 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 15-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim is directed to specific plasmids. Since the plasmids are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plasmids are not so obtainable or available, a deposit of microorganism containing said plasmids may satisfy the requirements of 35 USC 112. The specification does not disclose a repeatable process to obtain the plasmids and it is not apparent if the plasmids are readily available to the public. Thus, a deposit is required for enablement purposes.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
(d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,
(e) the deposit will be replaced if it should ever become inviable.

Note that because the entire sequence of pMSK49 is given in SEQ ID NO:27 (see the Brief Description of Figure 34), pMSK49 is not included in this rejection.

8. Claims 1-2, 5 and 8-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a multitude of recombinant DNA constructs for expressing proteins in plastids, wherein the construct comprises a 5' regulatory sequence comprising a downstream box element.

The specification appears to describe a potential downstream box as any sequence that can basepair with the 26 base long anti-downstream box region by as few as 5 exact matches and 3 weak G-U matches. The specification does not describe which of these sequences would actually function as downstream box sequences.

Hence, Applicant has not, in fact, described DNA molecules that encode plastid downstream box seuqences within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

See *Univ. of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997):

> The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical

> characteristics; in other words, it thus does not describe human insulin cDNA .... Accordingly, the specification does not provide a written description of the invention ....

and at pg 1406:

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.
> ... A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.
> ... the claimed genera of vertebrate and mammal cDNA are not described by the general language of the '525 patent's written description supported only by the specific nucleotide sequence of rat insulin.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

> A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials .... Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by it principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

9. Claims 1-2, 5 and 8-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA constructs comprising some plastid downstream box sequences, does not reasonably provide enablement for DNA constructs comprising all plastid downstream box sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to DNA constructs comprising a 5' regulatory region operably linked to a nucleic acid encoding a heterologous protein, wherein the 5' regulatory region comprises a promoter, a leader sequence, and a downstream box, wherein the 5' regulatory region enhances transnational efficiency of an mRNA.

The instant specification, however, only provides guidance for identification of potential downstream boxes in plastid mRNAs (pg 23-24), construction of a variety of 5' regulatory regions, including that of PrrnLT7g10+DB/Ec (SEQ ID NO:14), which comprises the Prrn promoter, the T7 phage gene 10 leader and the E. coli downstream box (pg 24-39); testing expression from these 5' regulatory regions - PrrnLT7g10+DB/Ec works well, while constricts comprising a perfect plastid downstream box worked less well (pg 39-50). The specification also teaches successful transformation of tobacco plastids with bar-gene containing constructs, including one comprising SEQ ID NO:14 (pg 61-73) and successful transformation of tobacco and rice plastids with GFP fusion protein-gene containing constructs (pg 73-93).

The instant specification fails to provide guidance for the full scope of sequences that comprise downstream boxes for use in 5' regulatory regions that enhance transnational efficiency of an mRNA.

Based on the guidance in Figure 2 it appears that a downstream box is merely any sequence that can basepair with the 26 base long anti-downstream box region by as few as 5 exact matches and 3 weak G-U matches. This would encompass almost any sequence. The specification does not teach the full scope of sequences that would actually function as downstream box sequences.

Given the claim breath and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate DNA constructs comprising a 5' regulatory region operably linked to a nucleic acid encoding a heterologous protein, wherein the 5' regulatory region comprises a promoter, a leader sequence, and a downstream box, wherein the 5' regulatory region enhances transnational efficiency of an mRNA.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-2, 4-6, and 8-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 1 is indefinite in its recitation of "higher plants" in line 1. It is unclear what plants are considered higher.

It is unclear in claim 1, lines 2 and 6-7, what the protein is heterologous to - the plant? the promoter? the leader? the downstream box element?

Claim 1 lacks antecedent basis for the limitation "said chimeric regulatory region" in line 7.

The term "enhancing" in claim 1, line 7, is a relative term that renders the claim indefinite. The term "enhancing" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention. What is transnational efficiency enhanced relative to?

It unclear in claim 4 if the Markush group has six members (PrrnLT7g10+DB/Ec, PrrnLT7g10+DB/pt, PrrnLT7g10-DB, and SEQ ID NOs:14-16), or three (that is, if the SEQ ID NOs: refer to the sequences for each of PrrnLT7g10+DB/Ec, PrrnLT7g10+DB/pt, and PrrnLT7g10-DB). If the latter, it is suggested that the SEQ ID NOs: be placed in parenthesis. Additionally, the claim lacks an --and-- before the last member of the group.

Claim 8 lacks antecedent basis for the limitation "said synthetic bar nucleic acid" in lines 3-4. The claim is also indefinite in its recitation of "nucleic acid having selected". Word(s) appear to be missing from the claim. It is also unclear if the claim language is open or closed; thus it is unclear if the nucleic acid comprises SEQ ID NO:19 or 20 or if it consists of one of those sequences.

Claim 10 is indefinite in its recitation of "said fusion protein having a first and second coding region" in lines 2-3. First, proteins do not have coding regions; only nucleic acids do. Second, does Applicant mean that the (nucleic acid encoding) the fusion protein is comprised of two operably linked coding regions, or does Applicant mean that the fusion protein is encoded by more than one coding region?

Claim 10 is indefinite in its recitation of ""said first coding region encoding a selectable marker gene" in lines 5-6. Coding regions do not encode genes; genes are coding regions themselves.

Claim 12 is indefinite in its recitation of "said fusion protein consisting of an aadA coding region operably linked to a green fluorescent protein coding region." Again, proteins do not have coding regions.

Claim 13 lacks antecedent basis for the limitations "said aadA coding region" and "said green fluorescent protein coding region". It is suggested that the claim be made dependent upon claim 12.

Claim 13 is indefinite in its recitation of ""having" in line 4. It is unclear if the claim language is open or closed; thus it is unclear if the peptide linker comprises SEQ ID NO:104 or 105 or if it consists of one of those sequences.

Claim 14 is indefinite in its recitation of "said construct having a sequence selected from the group of SEQ ID NOS:21-25 and 27." The claim is indefinite in its recitation of ""having" in line 2. It is unclear if the claim language is open or closed. Does Applicant mean that the entire sequence of the constrict consists of SEQ ID NOs:21-25 or 27 or that the construct comprises one of those sequences? Second, SEQ ID NOs:21-25 are FLARE coding sequences, not entire plasmids, while SEQ ID NO:27 is the entire sequence for the plasmid pMSK49. Thus, the members of the group are very different, unequal sequences.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1-2 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Svab et al (1993, Proc. Natl. Acad. Sci. USA 90:913-917) taken with the evidence of Maliga et al (US Patent 5,877,402, filed January, 1994).

Svab et al teach a plastid transformation vector comprising a 5' regulatory region operably linked to a nucleic acid encoding a heterologous protein (aadA), wherein the 5' regulatory region comprises the Prrn promoter, a leader sequence comprising a ribosome binding site, and a downstream box within the aadA coding region (Figure 1). The 5' regulatory region

would enhance translation of the heterologous protein. Maliga et al teach the coding sequence for aadA (Fig. 20C); the downstream box aligns with the plastid anti-downstream box (ADB) at least as follows:

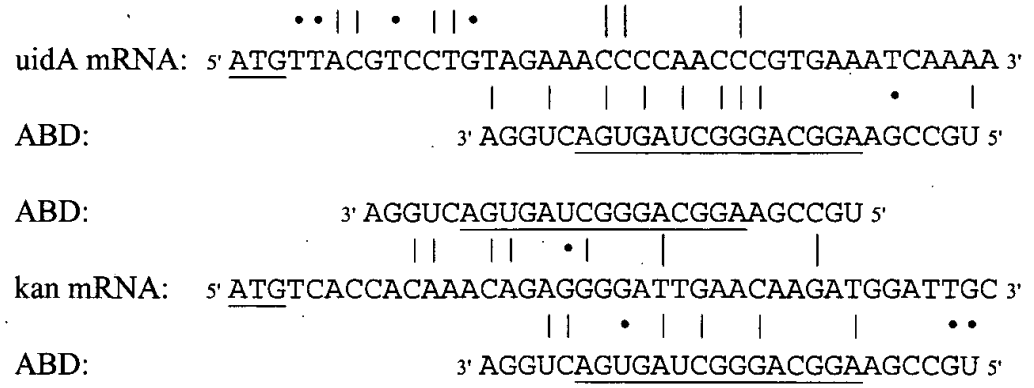
```
ABD:           3' AGGUCAGUGAUCGGGACGGAAGCCGU 5'
                   •|    | •   • |||    |
aadA mRNA: 5' ATGAGGGAAGCGGTGATCGCCGAAGTATCGAC 3'
                        |•|| |• • |    |• |
ABD:                3' AGGUCAGUGAUCGGGACGGAAGCCGU 5'
```

14. Claims 1-2, 5 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Maliga et al (US Patent 5,877,402, filed January, 1994) taken with the evidence of Jefferson (1993, GenBank Accession No. A00196).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Maliga et al teach plastid transformation vectors comprising a 5' regulatory region operably linked to a nucleic acid encoding a heterologous protein (aadA, uidA or kan), wherein the 5' regulatory region comprises the Prrn, psbA or rps16 promoters, a leader sequence, and a downstream box within the aadA, uidA or kan coding regions (Figures 5, 11, 18-20, 22-2, 26, 28A). Kan encodes a fusion protein of 5 amino acids of Rubisco large subunit and the NPTII polypeptide (column 40, lines 1-3). The 5' regulatory region would enhance translation of the heterologous protein. Jefferson teaches the sequence of the uidA gene. The alignment of the aadA downstream box with the ADB is shown above; the uidA and kan downstream boxes align with the ADB at least as follows:

```
ABD:           3' AGGUCAGUGAUCGGGACGGAAGCCGU 5'
```



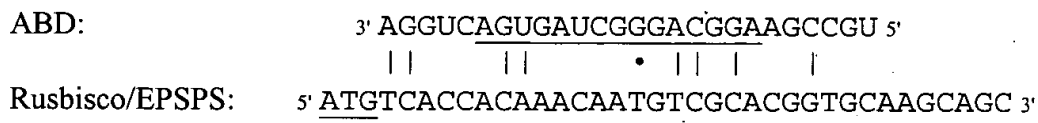
15. Claims 1-2, 5 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by McBride et al (US Patent 6,271,444, filed July 1998) taken with the evidence of Barry et al (1997, US Patent 5,627,061).

McBride et al teach plastid transformation vectors comprising a 5' regulatory region operably linked to a nucleic acid encoding a heterologous fusion protein, wherein the 5' regulatory region comprises a promoter (Prrn or T7 phage gene 10), a leader sequence (rbcLRBS or T7 phage gene 10 ribosome binding site), and a downstream box within the fusion protein coding region (see below) (column12, line 62, to column 17, line 7). The 5' regulatory region would enhance translation of the heterologous protein.

One fusion protein comprises 5 amino acids of Rubisco large subunit and CP4 EPSPS (column 13, lines 12-17). The DNA encoding the first5 amino acids of Rubisco is taught above and Barry et al teaches the sequence encoding CP4 EPSPS (Figure 3).

Another fusion protein comprises GUS (uidA) and aprotinin (column 16, lines 59-62).

The alignment of the uidA downstream box with the ADB is shown above; the Rusbisco/EPSPS downstream box aligns with the ADB at least as follows:



ABD: 3' AGGUCAGUGAUCGGGACGGAAGCCGU 5'

16. Claim 4, to the extent it reads on SEQ ID NO:14, is free of the prior art, given the failure of the prior art to teach or suggest a 5' regulatory region comprising SEQ ID NO:14. Claims 8 and 10-14 are free of the prior art, given the failure of the prior art to teach DNA construct comprising a 5' regulatory region operably linked to a synthetic bar DNA of SEQ ID NO:19 or 20 or a DNA encoding a fusion protein between a selectable marker and GFP, wherein the 5' regulatory region comprises a promoter, a leader sequence, and a downstream box. Claims 15-17 are free of the prior art, given the failure of the prior art to teach of suggest plastid transformation vectors pHK38(A), pMSK48, pMSK49 or pMSK35.

Conclusion

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
June 13, 2003